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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/844,731	04/21/1997	STALEY A. BROD	D5716-CIP3	7636

27851 7590 11/29/2004

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EXAMINER

SEHARASEYON, JEGATHEESAN

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 11/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/844,731	BROD, STALEY A.	
	Examiner	Art Unit	
	Jegatheesan Seharaseyon	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-11 and 16-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-11 and 16-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/9/2004 has been entered. An action on the RCE follows.

2. The Art Unit location and the examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1647.

3. Claims 18 and 16 have been amended. Therefore, Claims are 8-11 and 16-22 are pending.

4. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

5. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Rejections - 35 USC § 102(e), maintained

6. The rejection of Claims 8, 9, 11, 16, 17, 19, 20 and 22 under 35 U.S.C. 102(e) as being anticipated by Sobel (U.S. Patent No: 5,780,021) is maintained. Applicant's arguments have been fully considered but are not found to be persuasive. Further, Applicant in the response filed 11/3/2003 indicate that only claims 8-11 and 16-18 are pending in the Application. In fact the Application contains claims 8-11 and 16-22.

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Contrary to Applicant's assertion, claims 19-22 are drawn to reducing the blood glucose in an animal (see page 7 of response), which is inherent to the administration IFN- α as described by Sobel. Sobel also discusses the administrations being once per day to once per week. This also includes the administration every other day as claimed in claim 11 of the instant invention.

Applicant's arguments filed 11/03/2003 with respect to Sobel is based on the fact that the examples "do not provide an enabling disclosure for oral administration", that patentee's statements are broad and that Sobel does not provide for oral administration and "for ingestion". These have been adequately addressed in the previous Office Action dated 03/08/2004 (see page 4).

Applicant's arguments with respect to claims 19-22 that Sobel cannot anticipate them because it lacks enabling disclosure for oral administration as been addressed above and on page 4 of the Office Action dated 03/08/2004. Therefore, rejection of claims 8, 9, 11, 16, 17, 19, 20 and 22 under U.S.C 102(e) as being anticipated by Sobel (U.S. Patent No: 5, 780, 021) is maintained.

Claim Rejections - 35 USC § 103

7. The rejection of claims 8-11 and 16-22 under 35 U.S.C. 103(a) as being unpatentable over Sobel (U.S. Patent No: 5,780,021) in view of Cummings (U.S. Patent No: 5, 019, 382) is withdrawn in favor of the rejection of claims 10, 18 and 21 under 35 U.S.C. 103(a) as being unpatentable over Sobel (U.S. Patent No: 5,780,021) in view of Cummings (U.S. Patent No: 5, 019, 382) and Cummings (U.S. Patent No: 4, 497, 795). Applicant's arguments filed on 11/03/2003 have been fully considered but are not

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persuasive for reasons set forth in the Office Action of 03/08/2004. The instant rejections cover the dosage used by the Applicant to reflect the decision of BPA&I (9/6/2002). Sobel's teachings have been discussed in paragraph 2 of 03/08/2004 Office Action and above in paragraph 6. The reference does not teach dosage ranges described in claims 10, 18 and 21. Cummings describes the oral administration of about 0.1 to about 5 IU/lb per day of interferon (U.S. Patent No: 5, 019, 382, abstract). This is equivalent to about 0.22 to about 11IU/kg. Cummings also describes that 1 unit \cong 0.1IU (column 3, lines 54-55). In addition, Cummings (U.S. Patent No: 4, 497, 795) teaches the oral administration of 5,000 to 50, 000 units of interferon per Kg body weight (see claim 15). This is equivalent to about 500 to 5000 IU/Kg. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made to modify the interferon doses of Sobel to those taught by Cummings with expectation of treating IDMM patients. One of ordinary skill in the art would have been motivated to use interferon in the doses recommended by Cummings et al to treat IDMM with the expectation of success as because Cummings(U.S. Patent No: 5, 019, 382) teaches the treatment of autoimmune disorder which includes IDMM. Therefore, the instant claims are *prima facie* obvious over Sobel (U.S. Patent No: 5,780,021) in view of Cummings (U.S. Patent No: 5, 019, 382) and Cummings (U.S. Patent No: 4, 497, 795)

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claim 8-11 and 16-18 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8a. Claims that recite the "at-risk populations", such as claim 8 and 16, are indefinite as there is no limiting definition of such in the specification, and the metes and bounds of that which at-risk populations are unclear. Claim 9-11, 17 and 18 are rejected insofar as it is depended on rejected claims 8 and 16.

9. No claims are allowable.

Contact Information

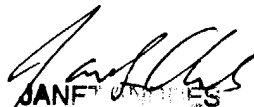
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JSS 11/04


JANET M. JONES
PRIM. EXAMINER